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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,118	06/28/2000	R. C. Quijano	VENPROO.007C1	6405

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/605,118

Applicant(s)

QUIJANO ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-36, 39-41 and 51-117 is/are pending in the application.
- 4a) Of the above claim(s) 39-41, 53-58, 61, 62, 74-79, 82, 83, 95-100, 103, 104, 116 and 117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-36, 51, 52, 59, 60, 63-73, 80, 81, 84-94, 101, 102, 105-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/02 has been entered.

Election/Restrictions

Applicant's election without traverse of Group I (valved prosthesis) and Species I (bifurcated prosthesis) in Paper No. 14 is acknowledged.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Ways to fix tissue

Species A: chemically.

Subspecies a: an aldehyde.

Subspecies b: a polyepoxy compound.

Species B: using gamma radiation.

Means of attaching and forming a seam

Species 1) stitching.

Subspecies I: a single pass.

Subspecies II: multiple passes.

Subspecies III: non-unravellable.

Subspecies IV: discrete.

Species 2) laser beam.

Species 3) biological sealant.

Species 4) chemical sealant.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and subspecies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 30,63,84,108 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

During a telephone conversation with Daniel Latham on 12/6/02 a provisional election was made without traverse to prosecute the invention of Species A, Subspecies a, Species 1, and Subspecies I, claims 30-36,51,52,59,60,63,64-73,80,81,84-94,101, 102,105-115. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-41,53-58,61,62,74-79,82,83,95-100,103,104,116,117 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Terminal Disclaimer

The terminal disclaimer filed on 6/19/02 disclaiming the terminal portion of any patent granted on this application that would extend beyond the expiration date of US 6,110,201 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 63-69,80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al. (5755734) in view of Peale (15192). Richter et al. discloses a Y-shaped body (Fig. 11) having a resulting inflow end with a greater cross-sectional area than the legs itself and is formed by two conduits forming a seam. Fig. 10 illustrates that the conduits have an inflow end and an outflow end. Richter also discloses the device is suitable for branching vessels and those that are weakened, col. 1, lines 10,21-23. Thus the inflow end is suitable for attachment to a heart and the outflow ends are suitable for attachment to pulmonary arteries. Since flat sheets are used to form the tubes and then joined at edges the seam formed inherently is smooth. However, Richter et al. do not disclose a valve in either of the conduits. Peale teaches to place valves in tubular conduits for arterial purposes, col. 1, lines 9-12. Peale teaches that the valve shown in Fig. 1 is a vein valve, col. 1, lines 21-23. Peale also teaches that the valves are sufficiently strong to withstand pressure (col. 2, lines 92-97), thus they are capable of opening at 1mm Hg and can withstand pressures about 200mm Hg. It would have been obvious to one of ordinary skill in the art to place a valve as taught by Peale in the bifurcated prosthesis of Richter in order to replace a damaged or dysfunctional valved section in a patient's vascular system. Regarding claims 68,69 Richter as modified by Peale do not disclose the cross-sectional area of the inflow end of the graft being greater than 22 or 28mm. It would have been an obvious matter of design choice

to have an inflow end with a cross-sectional area greater than 22 or 28 mm, since applicant has not disclosed that this diameter provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the dimension taught by Richter et al. or claims 68 or 69 dimensions because both ends perform the same function of providing an increased diameter at the inflow end, considering the typical size of an artery.

Claims 30-34,59,60,63-70,80,81,84-92,101,102,105-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Quijano et al. (5500014) in view of Richter et al. '734. Quijano et al. disclose valvular prostheses can be formed from a biological graft with a biological valve for defective blood vessels, col. 5, lines 10-15. Quijano also discloses the configuration depends on the intended use of the prosthesis (col. 8, lines 5-6) and also that valved conduits are needed to repair larger vessels, col. 14, lines 51-59. With respect to claims 34,67,88,112 the valves are fully capable of opening at pressures as low as 1mm Hg and remain sealably closed to withstand backflow pressure greater than 200 mm Hg. Quijano discloses that the tissue is fixed using an aldehyde, col. 10, lines 1-7. Quijano additionally discloses bovine or equine jugular veins can be used, col. 10, lines 12-14. However, Quijano does not disclose joining two segments for a bifurcated section of a damaged vessel. Richter et al. teach to join two conduits together at adjacent inflow ends (Fig. 10) forming a vascular prosthetic where the joined end has a cross-sectional area larger than any of the inflow ends of the conduits (Fig. 11) and the outflow ends can be used for a bifurcation. It would have

been obvious to one of ordinary skill in the art to use the teaching of joining two conduits together as taught by Richter with the grafts of Quijano in order to provide a vascular prosthesis for use in blood vessels comprising branched vessels. Thus in view of the combined teachings the inflow end is suitable for attachment to a heart and the outflow ends are suitable for attachment to pulmonary arteries.

Regarding claims 35,36,68,69,89,90,113,114 Quijano as modified by Richter do not disclose the cross-sectional area of the inflow end of the graft being greater than 22 or 28mm. It would have been an obvious matter of design choice to have an inflow end with a cross-sectional area greater than 22 or 28 mm, since applicant has not disclosed that this diameter provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the dimension taught by Quijano or claims 35,36,68,69,89,90,113,114 dimensions because both ends perform the same function of providing an increased diameter at the inflow end, considering the typical size of an artery.

With respect to claim 92, it would have been an obvious matter of design choice to have an angle formed of less than about 30 degrees between vessels, since applicant has not disclosed that this angle provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the angle taught by Quijano modified by Richter or claim 92's angle because both angle cuts permit the ability to attach inflow ends to form a greater diameter inflow end.

Claims 51,52,72,73,93,94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 as applied to claim 30 above, and further in view of Ehrenfeld (5156619). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose using stitching to form a seam in a bifurcated replacement vessel. Ehrenfeld shows (Figs. 3,5) that stitching in the form of single passes are used in attaching tubular conduits together for a graft. Ehrenfeld also teaches that stitching is done such that it is placed on an even continuous suturing surface, col. 3, lines 57-61. It would have been obvious to one of ordinary skill in the art to use stitching as the means to join graft segments of Quijano as taught by Richter in order to provide means of permanent attachment and reduce any chance of detachment of the joined segments.

Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 as applied to claim 63 above, and further in view of Mobin-Uddin (5078735). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose the angled slice less than 15 degrees at an inflow end. Mobin-Uddin show an angled slice in a graft for joining with another segment and the angle can be construed to be "about" 15 degrees. The use of "about 15 degrees" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited because *about* can mean $\pm 10\%$ or $\pm 0.5\%$. It would have been obvious to one of ordinary skill in the art to use the angled slice as taught by Mobin-Uddin to join graft segments of Quijano modified by

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Richter in order to provide an angled slice for attachment with another angled cut conduit.

Response to Arguments

Applicant's arguments with respect to claim 30 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738



Bruce Snow

Primary Examiner

Brian E. Pellegrino